UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Johns v. CR Bard et al.*,**
Case No. 2:18-cv-01509

DISPOSITIVE MOTIONS ORDER No. 2

Before the Court is Defendants', C.R. Bard, Inc. and Davol, Inc., motion for pre-verdict judgment as a matter of law under Federal Rule of Civil Procedure 50(a). (ECF No. 524.) Defendants argue that they are entitled to judgment on all of Plaintiff Steven Johns's claims. For the reasons below, Defendants' motion (ECF No. 524) is **DENIED**.

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation, alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1 (S. D. Ohio Sept. 1, 2020). This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. The Food and Drug Administration ("FDA") cleared it for use through the premarket notification § 510(k)

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1–6 (S. D. Ohio Sept. 1, 2020).

process in 2010 and later cleared it for use with the Echo Positioning System in 2011. It is a multicomponent device made of a mesh that consists of polypropylene, polyglycolic acid fibers, and a bioresorbable coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. *Id.* at *1–2.

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. *Id.* at *4. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body. *Id.* at *2–4. The crux of Plaintiff's claims is that the ST coating on the Ventralight ST resorbs too quickly. *Id.* at *13. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. *Id.* The following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. *Id.* at *6–25.

Trial commenced on August 2, 2021. (ECF No. 504.) Plaintiff rested his case on August 24, 2021. (ECF No. 523.) At the conclusion of Plaintiff's presentation of his case at trial, Defendants moved for judgment as a matter of law and filed a brief in support of their motion. (ECF No. 524.) The Court permitted Plaintiff to file a response. (ECF No. 534.)

II. Legal Standard

A party may move for judgment as a matter of law under Federal Rule of Civil

Procedure 50 when the opposing party has been fully heard and before the case is submitted to the jury. Fed. R. Civ. P. 50(a)(1) & (2). The Court may grant the motion if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1). The same standard for summary judgment motions applies to motions for judgment as a matter of law. *White v. Burlington N. & Santa Fe R. Co.*, 364 F.3d 789, 794 (6th Cir. 2004) (en banc) (quoting *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000)). The Court must review the entire record and "draw all reasonable inferences in favor of the nonmoving party, and [it] may not make credibility determinations or weigh the evidence." *McCombs v. Meijer, Inc.*, 395 F.3d 346, 352 (6th Cir. 2005) (quoting *Reeves*, 530 U.S. at 150). This means that the Court "must disregard all evidence favorable to the moving party that the jury is not required to believe." *White*, 364 F.3d at 794–95 (quoting *Reeves*, 530 U.S. at 151). "District courts should grant judgment as a matter of law only if a complete absence of proof exists on a material issue in the action, or if no disputed issue of fact exists on which reasonable minds could differ." *LaPerriere v. Int'l Union, United Auto., Aerospace, & Agric. Implement Workers of Am.*, 348 F.3d 127, 132 (6th Cir. 2003) (quoting *Clark v. Chrysler Corp.*, 310 F.3d 461, 479 (6th Cir.2002), *vacated on other grounds by Chrysler Corp. v. Clark* 124 S. Ct. 102 (2003); *see also In re E.I. Du Pont De Nemours & Co.*, No. 2:13-md-2433, 2015 WL 5822663, at *2 (S.D. Ohio Oct. 1, 2015).

III. Analysis[2]

Defendants argue that they are entitled to judgment as matter of law on all of Plaintiff's remaining claims, which they address in five categories: design defect

[2] When this opinion was issued, official transcripts were unavailable. An opinion incorporating citations to the final transcript will be issued as soon as practicable.

(negligence and strict liability theories), failure to warn (negligence and strict liability theories), fraud and/or negligent misrepresentation (negligence and strict liability theories), express and implied warranty, and punitive damages. (ECF No. 524 at PageID #27146.) For the reasons below, Defendants are not entitled to judgment as a matter of law on any Plaintiff's claims.

A. Design defect

Defendants argue that Plaintiff presents two theories of defect, polypropylene degradation and the premature resorption of the ST hydrogel layer, and that Plaintiff did not carry his burden to prove defect or causation under either theory. (*Id.* at PageID #27147–52.) Plaintiff has demonstrated that a reasonable jury could find a design defect in the Ventralight ST caused his injuries.

As an initial matter, the Court rejected Defendants' efforts to characterize Plaintiff's theory of design defect as two separate defects. Plaintiff does not espouse two separate theories but a single two-part theory of defect: "the resorption of the ST layer led to the exposure of polypropylene and . . . this led the premature exposure of the polypropylene to tissues in the body, causing oxidization and resulting in adhesions." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F Supp. ----, Nos. 2:18-md-2846, 2:18-cv-01509, 2021 WL 486425, at *10 (S.D. Ohio Feb. 10, 2021). This analysis proceeds with Plaintiff's two-step theory of defect in mind.

First, evidence of design defect. Defendants argue that Plaintiff contends that all polypropylene is inherently unsafe, meaning there cannot be a design defect because the Ventralight ST is unavoidably unsafe. (ECF No 524 at PageID #27148.) This argument falters on the law and the evidence. Whether the Ventralight ST is unavoidably unsafe is

an affirmative defense. *Burningham v. Wright Medical Tech., Inc.*, 448 P.3d 1283, 1292 (Utah 2019). This means that Defendants bear the burden of proof at trial, and Defendants must show that the evidence presented at trial "is so powerful that no reasonable jury would be free to disbelieve it." *Surles v. Andison*, 678 F.3d 452, 455–56 (6th Cir. 2012) (quoting *Cockrel v. Shelby Cnty. Sch. Dist.*, 270 F.3d 1036, 1056 (6th Cir. 2001)). In order to obtain judgment, Defendants must show a reasonable jury could *only* find that "(1) when the product was made, it could not be made safe for its intended use even applying the best available testing and research, and (2) the benefits of the product justified its risk." *Burningham*, 448 P.3d at 1292. Defendants fall short of this. Defendants point to Dr. Mays's testimony that all propylene degrades, but this is not tantamount to an opinion that the Ventralight ST is unavoidably unsafe. Dr. Mays's testimony does not satisfy either prong.

Defendants assert Plaintiff's proposed non-polypropylene alternatives are not alternative designs as a matter of law. (ECF No. 524 at PageID #27148–49.) Dr. Grischkan and Dr. Babensee offered a variety of alternatives during their expert testimony, including non-resorbable barrier designs, non-polypropylene designs, and native tissue repairs. This is sufficient. Moreover, the Court rejected Defendants' argument that non-polypropylene devices are not alternative designs at the summary judgment stage. *In re Davol, Inc./C.R. Bard Inc.*, 2020 WL 5223363, at *10–11.

Defendants' other counterarguments do not alter this conclusion. Defendants argue that testimony from Plaintiff's experts is contradictory because that the experts did not all have the same alternative design recommendations. (ECF No. 524 at PageID #27149–50.) It is doubtful that this testimony presents contradictions, but even if it did, it simply shows material fact issues for the jury.

Defendants contend that Plaintiff did not present appropriate evidence about non-polypropylene alternative designs because "neither medical doctors who testified as part of Plaintiff's case-in-chief had any issues with polypropylene," referencing Drs. Jensen and Grischkan. (*Id.* at PageID #27149 n.3) Defendants misconstrue Dr. Grischkan's testimony; he opined that polypropylene degrades. Moreover, Dr. Jensen is not an expert on specific or general causation, and so he need not have testified specifically about the design defect.

Relatedly, Defendants argue that Plaintiff did not provide an alternative design for the ST coating, *i.e.*, Plaintiff did not "explain[ ] how Bard could have changed the design to make the ST coating last longer." (*Id.* at PageID #27149.) Plaintiff does not need to specifically provide an alternative design for the ST coating, however, because Plaintiff's theory of defect is two-fold. A reasonable jury could find an alternative design is sufficient if it addresses problems with either the polypropylene or the ST coating.

Second, causation. Defendants argue that Plaintiff has not demonstrated causation because Dr. Grischkan did not testify that he had issues with polypropylene, that a non-polypropylene material would have led to a different outcome, or how to make the ST coating last longer. (*Id.* at PageID #27151.) Again, Defendants disregard Dr. Grischkan's testimony. Dr. Grischkan opined that the Ventralight ST caused Plaintiff's injuries because the ST coating resorbed too soon, thus exposing Plaintiff to bare polypropylene. Dr. Babensee testified as to the degradation of polypropylene. This is sufficient for plaintiff to survive a motion for judgment as a matter of law. This is also consistent with the summary judgment opinion in this case. *In re Davol, Inc./C.R. Bard Inc.*, 2020 WL 5223363, at *13.

B. Failure to warn

Defendants contend that Plaintiff has not met his burden on this claim, specifically that Defendants had a duty to warn, the warning was inadequate, and the warning caused Plaintiff's injuries. (*Id.* at PageID #27154–59.) This is not borne out by the trial record.

First, duty to warn and adequacy of warning. Defendants contend that Plaintiff has not demonstrated that Defendants had a duty to warn of adhesions, a well-known complication. (*Id.* at PageID #27154–55.) They also argue that Plaintiff has not shown that the Ventralight ST's Instructions for Use ("IFU") inadequately warned of adhesions. (*Id.* at PageID #27154–58.) As this Court has noted before, however, the issue is not just adhesions but the early resorption of the ST coating. *In re Davol, Inc./C.R. Bard Inc.*, 2020 WL 5223363, at *21. It is a material issue of fact for the jury whether Defendants' duty to warn included not only a duty to warn of adhesions, but also of the premature resorption of the ST coating causing exposure of polypropylene to the viscera before reperitonealization, and whether the warning sufficiently apprised Dr. Jensen of this risk. The Court has held that Defendants had not shown that the IFU was adequate as a matter of law. *Id.* Defendants present no evidentiary or legal basis that justifies departing from the Court's prior holding.

Defendants raise several arguments to the contrary, but do not prevail. They argue that the IFU states that it will minimize risk which is an accurate statement and thus is a sufficient warning. (ECF No. 524 at PageID #27156–57.) But whether the warning was adequate in the face of some risk is an issue of fact for the jury. Defendants also point to a recent Utah Supreme Court decision clarifying that adequate warnings must "be of an intensity and at a level of specificity 'justified by the magnitude of the risk.'" *Feasel v.*

Tracker Marine LLC, --- P.3d ----, 2021 WL 3557633, at *5 (Utah Aug. 12, 2021) (quoting *House v. Armour of Am., Inc.*, 886 P.2d 542, 551 (Utah Ct. App. 1994)). Defendants argue because Plaintiff's adhesions were asymptomatic, the magnitude of risk is low, justifying a less specific and less intense warning. (ECF No. 524 at PageID #27157–58.) At most, *Feasel* adds an additional factual complexity to the case—the specificity justified by the magnitude of the risk. The Utah Supreme Court's decision does not necessitate judgment in favor of Defendants or show that no reasonable jury would find sufficient evidence to decide the claim in Plaintiff's favor.

Finally, causation. Defendants contend that Plaintiff has not introduced evidence showing that the warning caused his injuries. (ECF No. 524 at PageID #27158.) Specifically, they argue that Plaintiff has not proposed an alternative warning and has not shown that an adequate warning would have changed Plaintiff's outcome. First, neither Defendants provide nor can the Court find an authority requiring a plaintiff to expressly propose an alternative warning. *Cf. Feasel*, 2021 WL 3557633, at *4 (setting forth a three-element test for failure-to-warn claims that does not include proposing an alternative warning). Second, Dr. Jensen testified that had he known the Ventralight ST's hydrogel coating did not last 30 days, he would not have used the device.

Defendants argue that despite Dr. Jensen's testimony that he expected the ST barrier to last for 30 days, "what mattered to Dr. Jensen was not how long the barrier lasted, but that it was sufficiently there" to permit reperitonealization. (ECF No. 524 at PageID #27158–59.) Additionally, Dr. Jensen did not know how long reperitonealization takes. (*Id.* at PageID #27159.) How to interpret Dr. Jensen's testimony, specifically how to weigh his expectation that the coating last 30 days versus his requirement that the

barrier last long enough to permit reperitonealization, is patently a matter for the jury. That Dr. Jensen did not know the time period for reperitonealization simply goes to his credibility, pertinently here, whether he would have chosen to use a different device had he received an adequate warning.

C. Fraud and/or negligent misrepresentation

Defendants then move on to Plaintiff's fraud and misrepresentation claims. Defendants argue that Plaintiff has not offered evidence of scienter for fraud, that a non-disclosure cannot form a basis for misrepresentation, and that Plaintiff has not offered evidence that Dr. Jensen relied on Defendants' purported assertions. (*Id.* at PageID #27159–62.) The Court disagrees.

First, scienter. Plaintiff has submitted evidence that Defendants knew that the ST coating did not last for a period of time close to 30 days but represented that the coating could last as long as 30 days, specifically "less than 30 days." Defendants' main contention is that all of the evidence Plaintiff presented during his case is evidence that the "less than 30 day" is technically an accurate statement and therefore Defendants did not know the statement to be false. (*Id.* at PageID #27160.) Viewing the trial record in the light most favorable to Plaintiff, a reasonable jury could conclude that Defendants knew the "less than 30 days" statement was false given Defendants' knowledge the ST coating lasted only 7 days.

Second, non-disclosure. Defendants argue that Plaintiff's negligent misrepresentation claim is premised on a non-disclosure, *i.e.*, that Defendants did not disclose how long the ST coating actually lasted. (*Id.* at PageID #27161.) However, Dr. Jensen expressly testified that he relied on representations from Defendants that the ST

coating would last 30 days. Thus, a reasonable jury would have a sufficient evidentiary basis to find that Defendants made affirmative statements that the ST coating lasted 30 days.

Third, reliance. Dr. Jensen testified that he would not have used the Ventralight ST had he known that the ST coating did not last for 30 days. *Supra* Part III.B. Defendants argue that Dr. Jensen did not know the period for reperitonealization (ECF No. 524 at PageID #27161), but this simply shows an issue of credibility for the jury. *Supra* Part III.B.

D. Express and implied warranty

Defendants argue that Plaintiff has failed to meet his burden at trial with regard to his express and implied warranty claims. However, Plaintiff has satisfied his burden for his warranty claims.

For implied warranty, Defendants argue that Plaintiff's claims fail as a matter of law for the same reasons as Plaintiff's design defect and failure to design claims and that there is no evidence that the Ventralight ST was unfit for its ordinary purpose or was not merchantable. (ECF No 524 at PageID #27163.) Judgment on Plaintiff's product liability claims is inappropriate, *supra* Part III.A & B, and so this cannot be a basis for granting judgment as a matter of law on Plaintiff's implied warranties claims. Plaintiff also presented evidence that the Ventralight ST was unfit and unmerchantable because the ST coating did not last for a time period close to 30 days, which was necessary to ensure proper reperitonealization and thus the prevention of adhesions. Dr. Beatrice testified to this user need dealing with reperitonealization.

Defendants counter that Dr. Jensen testified that the Ventralight ST held Plaintiff's

hernia in place, meaning there is no evidence that the device is unfit or not merchantable. (ECF No 524 at PageID #27163.) Given the evidence just discussed, this only demonstrates an issue of fact for the jury. In the light most favorable to Plaintiff, he has presented evidence that the Ventralight ST was unfit for its ordinary purpose and unmerchantable because of the actual resorption period of the ST coating.

For express warranty, Defendants argue that the statements "within 30 days" or "in less than 30 days" are not affirmative statements of fact that are specific or definite enough to give rise to an express warranty. (*Id.* at PageID #27164.) "To qualify as an affirmation of fact, a statement must be objective in nature, *i.e.*, verifiable or capable of being proven true or false. Similarly, to be relied upon as a promise, a statement must be highly specific or definite." *Boud v. SDNCO, Inc.*, 54 P.3d 1131, 1135 (Utah 2002) (footnote omitted). Whether an express warranty exists, *i.e.*, whether the warranty is specific and definite, is typically an issue for the jury. *Graystone Pines Homeowners Ass'n on Behalf of Owners of Condominiums v. Graystone Pines, Inc.*, 652 P.2d 896, 900 (Utah 1982). Here, Dr. Jensen testified that he was specifically told by Defendants via sales representatives that the resorption period lasted 30 days. And Dr. Grischkan testified that from his perspective as an end user, the within or less than 30 days statement would still convey a promise that the resorption period was 30 days. On these bases, Plaintiff withstands judgment as a matter of law.

E. Punitive damages

Finally, Defendants argue that Plaintiff has not introduced clear and convincing evidence of punitive damages. First, they argue that a reasonable jury could not find by clear and convincing evidence that Defendants engaged in intentionally fraudulent

conduct or conduct that manifests a knowing and reckless indifference toward, and a disregard of, the rights of others. (ECF No. 524 at PageID #27165.) Second, Defendants contend that punitive damages are unavailable under Utah Code Annotated § 78B-8-203(1). A reasonable jury could find intentionally fraudulent or knowing and reckless conduct, and punitive damages are available under § 78B-8-203(1).

First, evidence of conduct. As explained earlier, Plaintiff has presented evidence of fraud such that a reasonable jury could conclude by clear and convincing evidence that Defendants' conduct was intentionally fraudulent. *Supra* Part III.C. Days of testimony have been devoted to the lack of data Defendants had to substantiate their 30-day claim, to Defendants' knowledge of this lack of scientific support, and to the fact that Defendants proceeded with the 30-day claim. The same evidence also would permit a reasonable jury to conclude that there is clear and convincing evidence that Defendants' conduct manifested a knowing and reckless indifference toward, and a disregard of, the rights of others. Plaintiff put forward evidence that Defendants knew the ST coating did not last long enough to permit reperitonealization to occur, thus exposing Plaintiff to an avoidable risk of adhesions.

Defendants argue that Plaintiff has not put forward evidence that Defendants knew of a risk posed by its conduct that had a high degree of probability of substantial harm to another. (ECF No. 524 at PageID #27166–67.) To prove that Defendants engaged in conduct that was knowing and reckless, Plaintiff must show a "high degree of probability" that the conduct would "result in substantial harm to another,' and the conduct must be 'highly unreasonable conduct, or an extreme departure from ordinary care, in a situation where a high degree of danger is apparent.'" *Behrens v. Raleigh Hills Hosp.*, 675 P.2d

1179, 1187 (Utah 1983) (citations omitted). Plaintiff has done so. For example, Dr. Grischkan testified that the exposure of bare polypropylene to unprotected viscera is always considered undesirable because it results in serious injuries, such as adhesions, bowel obstruction, and bowel fistula. And given the evidence previously discussed that Plaintiff has introduced to show that Defendants knew of the serious risks to patients from bare polypropylene and that the ST coating lasted far less than 30 days, a reasonable jury could find this is highly unreasonable conduct where a high degree of danger is apparent.

Second, availability of damages. Defendants urge the Court to revisit its earlier decision that punitive damages are available under § 78B-8-203(1) when the medical device has undergone the 510(k) process. (ECF No. 524 at PageID #27167.) Defendants argue that the Court overlooked the fact that the Ventralight ST is a Class II device, meaning the FDA "could provide reasonable assurance[s] of the safety and effectiveness of surgical hernia mesh. (*Id.* at PageID #27168 (citations omitted).) This is unpersuasive. The Court relied on *Burningham* to conclude that punitive damages are available under these circumstances. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 5223363, at *24–25. The Utah Supreme Court in *Burningham* held that Class II medical devices cleared by the 510(k) process have not been evaluated by the FDA for safety and have no safety approval from the FDA. 448 P.3d at 1290. This reasoning led the Court to reject Defendants' argument that "compliance with FDA regulations precludes punitive damages as a matter of law." *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 5223363, at *25. Considering this authority, the Court will not revisit its previous determination.

IV. Conclusion

Accordingly, Defendants' motion for judgment as a matter of law (ECF No. 524)

is **DENIED**.

IT IS SO ORDERED.

9/2/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE